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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,413	02/08/2001	Bernard J. Banks	PC10901A	9774

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/779,413	<b>Applicant(s)</b> BANKS ET AL.	
	<b>Examiner</b> Raymond J Henley III	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-11 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-11, 17 and 18 is/are rejected.
- 7) ☒ Claim(s) 7, 15 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**CLAIMS 1-5, 7-11 AND 15-18 ARE PRESENTED FOR EXAMINATION**

Applicants' Amendment filed October 26, 2004 has been received and entered into the application. Accordingly, claims 1 and 10 have been amended; claim 6 has been canceled; and claims 15-18 have been added.

In view of the amendments, the rejection of claims 1-9 under 35 U.S.C. § 112, first paragraph, as set forth in the previous Office action dated July 29, 2004 at pages 2-3, is withdrawn.

***Claim Objection***

Claims 7, 15 and 16 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance. These claims are directed to compounds for which unexpected results have been demonstrated. Such results have been identified and discussed in the previous Office actions and thus no further comment is deemed necessary.

***Claim Rejection - 35 USC § 103***

Claims 1-5, 8-11, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al. '719 and Harada et al. '938, each of record, for the reasons of record as set forth in the previous Office action at pages 3-4, as applied to claims 1-11.

Applicants' arguments at pages 6-7 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

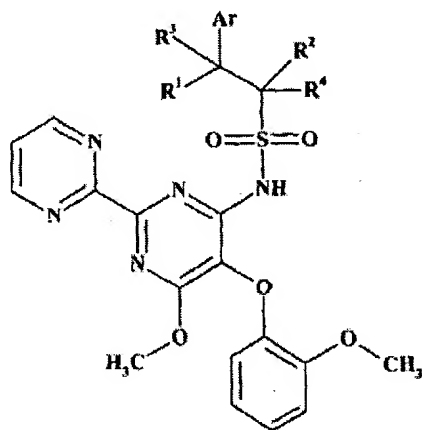
In particular, Applicants have argued that the species of compounds tested for activity are representative of the genus of the claims as amended. In support of this argument, applicants have stated "the Ar group has been limited to optionally substituted phenyl and optionally

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substituted naphthyl. In addition, the substituents on Ar have been limited to six preferred types of substituents. The claims, as amended, are therefor representative of the tested compounds.”.

In further support of their position, Applicants have pointed out the Office’s guidelines for examining applications which contain claims to a species or a subgenus of chemical species or subgenus, i.e., MPEP 2144.08.

As previously noted on the record, the Examiner acknowledges that unexpected results have been demonstrated. These results, however, do not provide a basis for concluding that the claimed subject matter would not have been obvious because the results are limited to two single compounds, i.e., compounds having the structure:



wherein, taken as a whole, the variables R and Ar represent either a phenyleth~~ane~~ or phenyleth~~ene~~ moiety, i.e., the Ar group is an unsubstituted phenyl, while the claims subject to this rejection encompass the compounds above where “Ar” may be either phenyl or naphthyl and may be unsubstituted or substituted by one or more groups selected from C<sub>1</sub>-C<sub>6</sub> alkyl, halo, C<sub>1</sub>-C<sub>6</sub> alkoxy, CO<sub>2</sub>H, C<sub>1-6</sub> alkoxy carbonyl, and CF<sub>3</sub>.

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Stated in another manner, applicants' claims [assuming for the purpose of illustration that (i) "halo" represents four substituents, i.e., F, Cl, Br and I; (ii) a phenyl ring may be substituted in 5 positions; and (iii) applicants' variables represent 23 possible substituents, i.e., C<sub>1</sub>-C<sub>6</sub> alkyl = 6 substituents, halo = 4 substituents, C<sub>1</sub>-C<sub>6</sub> alkoxy = 6 substituents, CO<sub>2</sub>H = 1 substituent, C<sub>1-6</sub> alkoxycarbonyl = 6 substituents, and CF<sub>3</sub> = 1 substituent] in only the case where Ar is phenyl, i.e., not accounting for where Ar is naphthyl, encompass 5 (positions of substitution) x 23 (possible substituents at position 1 of the phenyl ring) x 23 (possible substituents at position 2 of the phenyl ring) x 23 (possible substituents at position 3 of the phenyl ring) x 23 (possible substituents at position 4 of the phenyl ring) x 23 (possible substituents at position 5 of the phenyl ring) or 5 x 23 x 23 x 23 x 23 x 23 or 32,181,715 possible compounds. Applicants have demonstrated results of only 2 compounds and clearly these results are not representative of results that would occur with the 32 million+ claimed compounds.

Applicants' mere allegation that the results are commensurate in scope with claimed subject matter does not replace sound scientific reasoning or an objective showing of results.

In this regard, the Examiner cites MPEP 2144.08(II)(B) which reads in-part:

"When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a prima facie case of obviousness. *Id.* For example, a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of

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a claimed range would be sufficient to rebut a prima facie case of obviousness if a skilled artisan 'could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof.' *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the probative value thereof.). But see, *In re Grasselli*, 713 F.2d at 743, 218 USPQ at 778 (evidence of superior properties for sodium containing composition insufficient to establish the non-obviousness of broad claims for a catalyst with 'an alkali metal' where it was well known in the catalyst art that different alkali metals were not interchangeable and applicant had shown unexpected results only for sodium containing materials); *In re Greenfield*, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (evidence of superior properties in one species insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds); *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (one test not sufficient where there was no adequate basis for concluding the other claimed compounds would behave the same way).” (emphasis added). Here, Applicants have tested only two compounds and there is no adequate basis of record for concluding that the other claimed 32+ million compounds would behave in the same way.

Further, the showing of unexpected results is dependent on and related solely to how the compounds are used and thus is only representative of the claimed methods of treatment. The showing does not demonstrate in any manner that the claimed formulation possesses characteristics that would not have been expected by one of ordinary skill in the art. Compositions are not limited by their intended use and thus results directed to a particular

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intended use of that composition are not germane to a conclusion of whether or not the composition would have been obvious.

For the above reasons, the claims are deemed properly rejected.

None of the claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

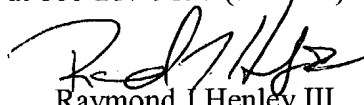
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

December 20, 2004